Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13277

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MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

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Form Approved OMB No 0910-0291 Expires 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 95855
13277

A. Patient information

1. Patient identifier	2 Age at time of event: 32 or Date of birth: [redacted]	3 Sex	4 Weight
In confidence		☐ female ☑ male	190 lbs or ____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☑ Product problem (e g , defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: Became sick

3. Date of event (mo/day/yr): 01-07-99

4 Date of this report (mo/day/yr): 01-08-99

5 Describe event or problem

Purchase done on 11-20-97, However it was for a gift for Christmas. Which was given to him for a present He took the supplement as directed and after awhile became ill, Headach, stomach sickness etc. I went to the [redacted] Mall where I purchased it with receipt & product. The girl told me since it was pass the 30 days she couldn't. I tried to explain about given it as a Christmas gift she refused.

6. Relevant tests/laboratory data, including dates

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MEDWATCH CTU

7 Other relevant history, including preexisting medical conditions (e g , allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

N/A

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)
#1 Metabolife 356
#2

2 Dose, frequency & route used
#1 1½ Pills
#2

3 Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5 Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)
#1
#2

7 Exp. date (if known)
#1
#2

8 Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

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D. Suspect medical device

1. Brand name: Metabolife 356
2 Type of device:
3 Manufacturer name & address: Metabolife 356 [redacted]

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

6
model #
catalog #
serial # H819
lot #
other #

5 Expiration date (mo/day/yr): 08-01

7 If implanted, give date (mo/day/yr):

8 If explanted, give date (mo/day/yr):

9 Device available for evaluation? (Do not send to FDA)
☑ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10 Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1 Name, address & phone # [redacted]

2 Health professional? ☐ yes ☒ no

3 Occupation: Housewife.

4 Also reported to
- ☐ manufacturer
- ☐ user facility
- ☒ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

CTU 95855

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

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BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

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